BOSE McKINNEY & EVANS LLP

CUSTOMER NUMBER 64108
111 Monument Circle, Suite 2700
Indianapolis, Indiana 46204
(317) 684-5000

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Pachl, et al.	Attorney Docket No. 9134-0414
Title: COATED TEST ELEMENTS	Examiner: Lyle Alexander
Serial No.: 10/581,409	Confirmation No. 3752
Filed: September 20, 2006	Art Unit: 1773

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Martin Frank, hereby declare that:

1. I am a joint inventor ("inventor") of the pending claims of the above-identified application.

2. I have significant experience in the technology area of the application, which includes diagnostic devices such as biosensors that are used to test body fluid samples such as whole blood. I have had significant experience in the research and development of such biosensors, and, due to my experience and education, I possess a strong understanding of the fluid properties of blood and the physical properties of the various parts of a biosensor that contact and interact with blood and other body fluid samples. My experience in this area rises to at least the level of one of ordinary skill in the art.

3. I have the following relevant degrees/education:

Diploma of Biomedical Engineering, FH-Aachen, Germany

4. I have worked in the area of developing biosensors and their manufacturing processes for 17 years.

5. I am a named inventor or author on the following patents, publications and/or literature articles:

US Patent No. or US Patent Application No.	Title
5,281,395	"Test carrier analysis system"
7,510,682	"Test element analysis system"
2007/0110613	"Coated test elements"
7,101,169 2005/0023730	"Method and device for producing pouch-shaped or pot-shaped parts and use of the parts for accommodating samples or the like" "Pouch-shaped or pot-shaped parts and use of the parts for accommodating samples or the like"
7,763,470 2010/0278693	"Test element and method of use for analyzing body fluids" "Test Element for Analyzing Body Fluids"
2009/0090874	"Marking Method for the Reject Marking of Test Elements"

6. I understand that a Final Office Action ("Action") was issued by the United States Patent & Trademark Office ("Office") in the instant application on March 3, 2011. I also understand that the Action rejects currently pending claims 22-25, 29-36 and 40-42 as anticipated by U.S. Patent No. 6,441,898 to Markart ("Markart"). I also understand that claims 26-28 were rejected as obvious or lacking inventive step over Markart.

7. I also understand that our U.S. patent attorney, Michael C. Bartol, has discussed the pending claims with the U.S. Examiner, Mr. Lyle Alexander. I understand that from these discussions Mr. Alexander has requested documentation of the results achieved with my invention. In particular, I understand that Mr. Alexander has requested better quality representations of Figs. 3a – 3c of the instant application and my comments/explanation of these figures.

8. Submitted herewith as Exhibit A to my Declaration are Figs. 3a – 3c from the instant application in higher resolution than provided with the filing of the U.S. application. The figures shown in Exhibit A are true and accurate photos of test elements that were tested as described in the instant application. My explanation of the figures at Exhibit A and comments are as follows:

a. Test elements were produced according to WO 99/29429. These test elements are multi-layered and have an opening centered at the bottom edge of the elements as shown in the figures in Exhibit A. The opening extends into a capillary channel, which terminates in a test region.

b. In accordance with the teachings of our invention, the test elements shown in Fig. 3a were coated on the outside with a lotus effect spray. In particular, the surface of the carrier foil of the test elements was coated with hydrophobic nanoparticles to form a hydrophobic structured surface comprising elevations and depressions, the height of the elevations ranging from about 50 nm to 100 µm. This treatment provides a hydrophobic structured surface around the application zone. The test elements were then immersed in a 10 µl drop of blood. After the test elements were removed from the sample, no blood could be seen in the area of the test elements surrounding the opening. This is consistent with Fig. 3a of the attached Exhibit A.

c. While the photos in Exhibit A are not high resolution, I hereby affirm that there was no blood visible in the area surrounding the channel openings on any of the test elements shown in Fig. 3a. It appeared from my observations that the hydrophobic structured surfaces we formed prevented blood from adhering to the area surrounding the opening and instead guided the blood sample into the channel.

d. The same type of test elements are shown in Fig. 3b. Instead of being formed with a lotus effect surface in accordance with the instant invention, however, a standard wax with known hydrophobic properties was used as a coating. This standard wax did not possess a hydrophobic structured surface around the application zone comprising elevations and depressions, the height of the

elevations ranging from about 50 nm to 100 μm. These test elements were immersed in a 10 μl drop of blood and then removed, as described above. It can be seen in Fig. 3b that the blood sample spread and contaminated areas around the channel opening on all of the test elements shown in Fig. 3b.

e. The test elements shown in Fig. 3c were treated with a Teflon spray in the area surrounding the opening, but are otherwise the same as the test elements in Figs. 3a and 3b. This standard treatment with teflon did not provide a hydrophobic structured surface having elevations and depressions, the height of the elevations ranging from about 50 nm to 100 μm. These test elements were immersed in a 10 μl drop of blood and then removed, as described above. While the spreading of blood contamination on the samples of Fig. 3c was not as great as in the test elements of Fig. 3b, blood contamination of some portion of the area surrounding the channel opening was observed in all test elements shown in Fig. 3c.

f. While blood sample in the four test elements in the middle of Fig. 3c ($2^{nd} - 5^{th}$ test elements) may not appear to have contaminated areas around the channel opening, this is not the case. Instead, the contamination cannot be seen very well due to the low resolution of the photos in the attached Exhibit. For example, if one looks closely at the next to the last (5^{th}) test element shown in Fig. 3c, contamination can be seen on both sides of the channel.

g. I hereby affirm that there was observable contamination in all of the test elements shown in Fig. 3c around the channel opening when I closely examined the actual test elements during the test that resulted in the photos in Fig. 3c.

9. Based upon my observations and testing of the test elements prepared in accordance with my invention, it is my belief that the inventive test elements, which have a hydrophobic structured surface in an area around the application zone as specified in claim 22, avoid contamination around the application zone and instead automatically guide the sample towards the channel opening. The performance of the inventive test elements compared to those shown in Figs. 3b and 3c was surprising and unexpected.

10. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Martin Frank

Martin Frank

19-Aug-2011

Date

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